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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
09/030,882	02/26/98	HANNA	M 1488.0950001

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EXAMINER	
LANDSMAN, R	
ART UNIT	**PAPER NUMBER**
1647	18

DATE MAILED: 12/20/00

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary	Application No.	Applicant(s)	
	09/030,832	HANNA ET AL.	
	Examiner	Art Unit	
	Robert Landsman	1647	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *27 September 2000* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *95-147* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *95-147* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. & 119(e).

Attachment(s)

15) ☐ Notice of References Cited (PTO-892)
16) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
17) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) *3/31/99* .
18) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
19) ☐ Notice of Informal Patent Application (PTO-152)
20) ☐ Other: .

DETAILED ACTION

1. Formal Matters

A. The Declaration under 37 CFR 1.131, filed 9/27/00, has been entered into the record.

B. Amendment D, filed 9/27/00, has been entered into the record.

C. Claims 95-147 are currently pending in the application. In the Office Action dated 3/27/00, the Examiner stated that there would be an undue search burden to search Groups I-III as Applicants requested. This response to the Applicants request was intended to be made final in that Office Action, but no statement of finality was made. For this reason, the restriction, as stated in the Office Action dated 3/27/00, is still deemed proper and is therefore made FINAL.

D. The Examiner appreciates the submission of the NCBI Entrez Nucleotide Queries (references AT16-AS20). The Examiner has initialed the Form PTO-1449 and has included a copy for the Applicants.

Withdrawn Rejection

1. Claim Rejections - 35 USC § 112, second paragraph

A. The rejections of claims 95-126 under 35 USC 112, second paragraph have been withdrawn since Applicants have pointed out that claims 95, 98, 101, 104, 115 and 117 recite 5% of the total amino acid residues.

B. The rejection of claim 127 is withdrawn since Applicants argue that the terms "first" and "second" are a necessary part of the Applicants' invention.

2. Claim Rejections - 35 USC § 102

A. The rejection of all claim under 35 USC 102(a) as being unpatentable over Davies et al. have been withdrawn in view of Applicants' submission of a Declaration under 37 CFR 1.132 stating that Davies and Hales did not contribute to the conception of the invention. Therefore, the Davies et al. reference is Applicants' own work published less than one year from the filing date of the present application.

B. The rejection of all claim under 35 USC 102(a) as being unpatentable over Garret et al. have been withdrawn in view of Applicants' submission of a Declaration under 37 CFR 1.131 stating that Applicants were in possession of their invention prior to the publication date of the Garret et al. reference. Applicants also provided convincing evidence that they were in possession of the invention before March 08, 1997.

3. Claim Rejections - 35 USC § 103

A. All rejections under 35 USC 103(a), have been withdrawn in view of Applicants' submission of a Declaration under 37 CFR 1.132 stating that Davies and Hales did not contribute to the conception of the invention. Therefore, the Davies et al. reference is Applicants' own work published less than one year from the filing date of the present application.

Maintained Rejections

1. Claim Rejections - 35 USC § 112, second paragraph

A. Claims 95-126 remain rejected under 35 USC 112, second paragraph for the reasons already of record on page 3 of the Office Action dated 3/27/00. The Examiner realizes that the Applicants made the necessary changes regarding the "Bestfit" program. However, after further consideration, it is suggested that the Applicants remove any reference to the program altogether. The amended claims could recite, for

example, "...wherein % identity is calculated over the full length of amino acids 1-260 of SEQ ID NO:42 and that permit gaps of up to 5%..."

New Rejections

1. Claim Rejections - 35 USC § 101

35 U.S.C. 101 reads as follows:

> Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

A. Claims 95-147 are rejected under 35 U.S.C. 101 because the claimed invention is not supported by a specific, substantial and credible asserted utility or a well established utility. These claims are drawn to an invention with no apparent or disclosed patentable utility. This rejection is not in conflict with the current utility guidelines. The instant application has provided a description of a nucleotide to a partially isolated protein. However, the instant application does not disclose the biological role of this protein or its significance.

It is clear from the instant specification that the claimed polynucleotide encodes an "orphan receptor" in the art. There is little doubt that, after complete characterization, this protein will probably be found to have a patentable utility. This further characterization, however, is part of the act of invention and, until it has been undertaken, Applicants' claimed invention is incomplete.

The instant situation is directly analogous to that of which was addressed in Brenner v. Manson, 148 U.S.P.Q. 689 (Sus. Ct, 1966), in which a novel compound which was structurally analogous to other compounds which were known to possess anticancer activity was alleged to be potentially useful as an antitumor agent in the absence of evidence supporting this utility. The court expressed the opinion that all chemical compounds are "useful" to the chemical arts when this term is given its broadest interpretation. However, the court held that this broad interpretation was not the intended definition of "useful" as it

appears in 35 U.S.C. 101, which required that an invention must have either an immediate obvious or fully disclosed "real-world" utility. The court held that:

"The basic quid pro quo contemplated by the Constitution and the Congress for granting a patent monopoly is the benefit derived by the public from an invention with substantial utility," "[u]nless and until a process is refined and developed to this point - where specific benefit exists in currently available form – there is insufficient justification for permitting an applicant to engross what may prove to be a broad field," and "a patent is not a hunting license," "[i]t is not a reward for the search, but compensation for its successful conclusion."

The instant claims are drawn to a polynucleotide encoding a protein which has a yet undetermined function or biological significance. Applicants have hypothesized that this receptor is a member of the GABA receptor family of receptors. There is no actual and specific significance which can be attributed to said protein identified in the specification. Applicants have not disclosed that they are in possession of compounds which interact with this subunit of a GABA receptor, or that this subunit has activity. For this reason, the instant invention is incomplete. In the absence of a knowledge of the natural ligands or biological significance of this protein, there is no immediately obvious patentable use for it. To employ a protein of the instant invention in the identification of substances which bind to and/or mediate activity of the said receptor is clearly to use it as the object of further research which has been determined by the courts to be a non-patentable utility. Since the instant specification does not disclose a "real-world" use for said protein, then the claimed invention is incomplete and, therefore, does not meet the requirements of 35 U.S.C. 101 as being useful.

Therefore, since the isolated polynucleotide has not been shown to have any specific, substantial and credible asserted utility or a well established utility, the claimed protein, fragments of the polynucleotide or receptor, as well as vectors, host cells and method of producing the protein do not have any specific, substantial and credible asserted utility or a well established utility.

2. Claim Rejections - 35 USC § 112, first paragraph – lack of enablement

A. The specification is objected to and claims 95-147 are rejected under 35 U.S.C. 112, first paragraph, as failing to adequately teach how to use the instant invention. Specifically, since the claimed invention is not supported by a specific, substantial and credible asserted utility or a well established utility for the reasons set forth above, one skilled in the art clearly would not know how to use the claimed invention.

B. Claims 95, 98, 101 and 104, 107-117, 119-126 and 127-147 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for SEQ ID NO:42 does not reasonably provide enablement for polypeptides which are "at least 95% identical" to various amino acid segments of SEQ ID NO:42. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention commensurate in scope with these claims.

In In re Wands, 8USPQ2d, 1400 (CAFC 1988) page 1404, the factors to be considered in determining whether a disclosure would require undue experimentation include (1) the quantity of experimentation necessary, (2) the amount of direction or guidance presented, (3) the presence or absence of working examples, (4) the nature of the invention, (5) the state of the prior art, (6) the relative skill of those in the art, (7) the predictability or unpredictability of the art, and (8) the breadth of the claims.

These claims are rejected since they recite a "at least 95% identical" to various segments of SEQ ID NO:42. First, the breadth of the claims is too large with regard to Applicants claiming all proteins which are at least 95% identical to SEQ ID NO:42. Applicants have only provided guidance and working examples of the claimed segments of SEQ ID NO:42 and not of proteins which are at least 95% identical to various segments of SEQ ID NO:42. In addition, it is not predictable to one of ordinary skill in the art

what proteins which only comprise at least 95% identity to the disclosed segments of SEQ ID NO:42 would code for.

In addition, regarding claims 136-147, the breadth of the claims is too large with regard to the claimed fragments of SEQ ID NO:42. First, the specification does not provide any guidance or working examples of the use of fragments of SEQ ID NO:42 and it is not predictable to one of ordinary skill in the art which fragments of SEQ ID NO:42 can be used or how to use them.

Therefore, due to the large breadth of the claims regarding all fragments and proteins which are at least 95% identical to SEQ ID NO:42, or segments thereof, along with a lack of guidance and working examples of how to make and use these fragments and segments which are 95% identical to those of SEQ ID NO:42, or segments thereof, as well as the unpredictability in the art of how to make and use functional fragments and segments, the Examiner holds that undue experimentation would be necessary to practice the method of using fragments and segments of SEQ ID NO:42 as claimed.

3. Claim Rejections - 35 USC § 112, first paragraph – lack of written description

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

A. Claims 95, 98, 101 and 104, 107-117 and 119-126 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

These are genus claims. The term "% identical" can mean a nucleic acid molecule or protein having one or more amino acid insertions, substitution, or deletions to SEQ ID NO:42. The specification and claims do not indicate what distinguishing attributes are shared by the members of the genus. Thus

the scope of the claims includes numerous structural variants, and the genus is highly variant because a significant number of structural differences between genus members is permitted. Although these types of changes are routinely done in the art, the specification and claims do not provide any guidance as to what changes should be made. Structural features that could distinguish compounds in the genus from others in the protein class are missing from the disclosure. No common structural attributes identify the members of the genus. The general knowledge and level of skill in the art do not supplement the omitted description because specific, not general, guidance is what is needed.

Since the disclosure fails to describe the common attributes or characteristics that identify members of the genus, and because the genus is highly variant, SEQ ID NO:42 alone is insufficient to describe the genus. One of skill in the art would reasonable conclude that the disclosure fails to provide a representative number of species to describe the genus. Claims 96, 97, 99, 100, 102, 103, 105, 106 and 118 are objected to since they depend from rejected base claims.

Advisory information

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Robert Landsman whose telephone number is (703) 306-3407. The examiner can normally be reached on Monday - Friday from 8:00 AM to 5:00 PM (Eastern time) and alternate Fridays from 8:00 AM to 5:00 PM (Eastern time).

If attempts to reach the examiner by telephone are unsuccessful, the Examiner's supervisor, Gary Kunz, can be reached on (703) 308-4623.

Official papers filed by fax should be directed to (703) 308-4242. Fax draft or informal communications with the examiner should be directed to (703) 308-0294.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Robert Landsman, Ph.D.
Patent Examiner
Group 1600
December 18, 2000

Gary L. Kunz
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